

### **Remarks**

#### **Amendments to the Claims**

Claims 16-21 and 24-31 were pending in this application. Claims 16-21 are cancelled. Applicants expressly reserve the right to pursue protection of any or all of the cancelled subject matter in one or more divisional and/or continuation applications. Claims 24, 25, 27 and 28 are amended herein. Support for the amendment of claims 24 and 25 can be found throughout the specification and the original claims. Representative support can be found in the English language translation of the specification at least at page 18, lines 22-25, page 20, lines 30-35, page 23, lines 6-16, page 42, lines 18-27, referential example 25 and example 1a. Claims 27 and 28 are amended to correct typographical errors. No new matter is introduced by these amendments.

After entry of this amendment, **claims 24-31 are pending in the application.**

Reconsideration of the pending claims is requested.

#### **Prior Art Rejections** **Claims 16-21**

The Office has rejected claims 16-21 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,707,987 (Nakagawa *et al.*). Claims 16-21 are canceled herein rendering this rejection moot.

The Office has rejected claims 16-21 as anticipated under 35 U.S.C. § 102(e) or alternatively obvious under 35 U.S.C. § 103(a) over WIPO Publication No. WO 2004/096795 (Player *et al.*). Claims 16-21 are cancelled herein rendering this rejection moot.

#### **Claims 24-31**

The rejection of claims 24-31 under the theory of anticipation (under 35 U.S.C. § 102(e)) or obviousness (under 35 U.S.C. § 103(a)) over Player *et al.* is improper

M.P.E.P §§ 2112 III and 2113 lay out the circumstances under which a joint rejection under 35 U.S.C. § 102/103 alleging inherency can be made. M.P.E.P § 2112 III states that a rejection under 35 U.S.C. § 102/103 is appropriate “[w]here applicant *claims a composition* in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference [emphasis added].” Claims 24-31 are drawn to methods of treatment not compositions, therefore the Office’s rejection of claims 24-31 is improper in view of M.P.E.P § 2112 III.

A rejection under 35 U.S.C. § 102/103 may also be appropriate when the claimed subject matter is a product-by-process claim and “the lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established.” M.P.E.P § 2113, quoting *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Because the claims 24-31 are method claims, not product by process claims, a rejection of these claims cannot be made based on M.P.E.P § 2113.

Because the pending claims are neither product claims nor product by process claims, a rejection under 35 U.S.C. § 102/103 is therefore improper. Applicants request that this rejection be withdrawn.

The Office’s assertion that the burden of proof shifts to the applicants to show the prior art does not have the function of inhibiting viral replication is also misplaced. In attempting to shift the burden of proof to Applicants, the Office has relied on M.P.E.P § 2112 V to assert that “the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product.” M.P.E.P § 2112 V citing *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980). However, as this passage indicates, M.P.E.P § 2112 V is limited to claimed products and is not applicable to method claims. Because the claims at issue in the current case are method of treatment claims, this section of the M.P.E.P. is not applicable. For this additional reason, Applicants request that the rejection of claims 24-31 be withdrawn.

The claimed method of treating a viral infection in a subject in need of such treatment is not disclosed in the cited reference. To the extent the Office action is contending that the claimed compounds had inherent anti-viral activity, the rejection must still be withdrawn because the cited reference does not inherently show treating a viral infection by administering any compounds to a subject in need of such treatment.

Claims 24-31 are not anticipated by Player *et al.*

Even if the rejection under 35 U.S.C. § 102/103 using the rationale set forth in M.P.E.P. §§ 2112 III and 2113 were properly formulated, which Applicants have shown it is not, claims 24-31 are neither anticipated (under 35 U.S.C. § 102(e)) nor obvious (under 35 U.S.C. § 103(a)) over Player *et al.* The Office has rejected claims 24-31 as anticipated (under 35 U.S.C. § 102(e)) or obvious (under 35 U.S.C. § 103(a)) over Player *et al.* The Office contends that Player *et al.* discloses “methods to inhibit the activity of viral proteins, including those required for the virus listed in claims 27-31.” Applicants respectfully traverse this rejection.

Player *et al.* discloses certain aniline derivatives, pharmaceutically acceptable salts and hydrates thereof, and methods of inhibiting protein tyrosine kinase activity, in particular, the kinase activity of c-fms. Player *et al.* also discloses the treatment of diseases including cancer, inflammatory diseases, and cardiovascular diseases (see page 19, line 22 through page 20, line 3 and claims 13-16). However, contrary to the Office’s assertion, nowhere does Player *et al.* teach or suggest the treatment of a viral infection by administering any agent to a subject in need of treatment for a viral infection, much less the aniline derivatives recited in the pending claims.

For a reference to anticipate a claim “each element of the claim at issue is found, either expressly described or under the principles of inherency, in a single prior art reference or that the claimed invention was previously known or embodied in a single prior art device or practice.” *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983). Inherency requires that any information missing from the reference would nonetheless be known to be present in the subject matter of the reference, when viewed by persons experienced in the field of the invention. However, “anticipation by inherent disclosure is appropriate only when the reference

discloses prior art that must necessarily include the unstated limitation [or the reference] cannot inherently anticipate the claims.” *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002) (emphasis in original). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). A prior art rejection cannot be based on speculation about what Player *et al.* might have done, but did not report. Because Player *et al.* does not disclose the method step of “administering to the subject in need of treatment for the viral infection, in an amount effective to treat the viral infection,” the aniline derivatives as recited in claim 24 (the only independent claim) this reference cannot anticipate the pending claims. Because there is no basis in the cited reference for contending that Player *et al.* administered the agents to subjects in need of treatment for viral infection, Applicants request that the rejection of claims 24-31 be withdrawn.

Claims 24-31 are not obvious in view of Player *et al.*

Claims 24-31 recite methods for treating a viral infection in a subject. Player *et al.* does not teach any methods of treating viral infection. Because this reference does not teach or suggest each and every limitation present in claim 24 and all claims dependent therefrom there is no *prima facie* case of obviousness. A rejection based on “inherency” cannot support a finding of obviousness. An assertion of inherency implicitly acknowledges the absence of a teaching or suggestion of the claimed invention.

Furthermore, it could not be predictable that administration of the compounds disclosed in Player *et al.* could be used to inhibit viral infection in a subject. A reasonable expectation of success is required to support the assertion that a claim would have been *prima facie* obvious and that modification of the reference to yield the claimed subject matter would be predictable. M.P.E.P § 2143.02. As discussed above, Player *et al.* discloses certain aniline derivatives, pharmaceutically acceptable salts and hydrates thereof, and methods of inhibiting protein

tyrosine kinase activity, and in particular, the kinase activity of c-fms. C-fms has never been implicated in any viral process. Therefore, one of ordinary skill in the art would not have been able to predict with any reasonable expectation of success that compounds disclosed in Player *et al.* would inhibit viral infection. In light of the arguments and amendments presented herein, the Office has not met its burden in establishing a *prima facie* case of obviousness. Applicants request that the rejection of claims 24-31 be withdrawn.

### Concluding Remarks

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. The rejection of the pending claims as anticipated or obvious under 35 U.S.C. §§ 102/103 is improper. In addition, the claims are not anticipated or obvious, inherently or otherwise, because the prior art of record does not teach all the elements present in the claims. If for any reason the Examiner believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at the telephone number listed below.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600  
121 S.W. Salmon Street  
Portland, Oregon 97204  
Telephone: (503) 595-5300  
Facsimile: (503) 595-5301

By /Ian J. Griswold/  
Ian J. Griswold, Ph.D.  
Registration No. 57,338